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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,109	10/23/2003	Magnus Ohman	P03,0410	6570

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EXAMINER

PATEL, NATASHA

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/692,109

Applicant(s)

OHMAN, MAGNUS

Examiner

Natasha N. Patel

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☒ Claim(s) 1 and 8 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- Paper No(s)/Mail Date 23 October 2003 March 1, 2004
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 1 and 8 objected to because of the following informalities: Stimulation is misspelled as stipulation. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Levine et al. (US Patent 6,129,746).
4. Regarding Claim 1, Levine discloses a heart stimulating device comprising a pulse generator (see pulse generator 116, col. 5, lines 58-62) which emits stimulation pulses of variable energy content; a stimulation threshold measuring circuit (see sensor circuit 122) adapted to interact with a subject to which the stimulation pulses are delivered, to measure a stimulation threshold value in the subject; a timer (see timing and control 114) connected to the stimulation threshold measuring circuit for initiating multiple threshold searches at respective times wherein the timer varies an interval between successive threshold searches dependent on a result of at least a last-performed threshold search (see col. 7 lines 46-54); and a control unit (see processor 112) connected to the pulse generator and to the stimulation threshold measuring circuit

Art Unit: 3766

for causing the pulse generator to emit the stimulation pulses with an energy content dependent on the stimulation threshold value measured by the stimulation threshold measuring circuit (see Figure 1).

5. Regarding Claims 2 and 3, Levine discloses an increase in the interval if the stimulation threshold value did not change in the last-performed threshold search or a decrease in the interval if the stimulation threshold value did change in the last-performed threshold search (see Claim 1 and col. 9, lines 49-61). The examiner considers that timing and control 114 is responsible for providing crucial information to processor 112, which in effect determines whether the interval will be increased or decreased (see col. 5, lines 62-66). In other words, timing and control 114 increases and decreases the interval between threshold searches even though it may be indirectly. The examiner also considers a volatile output signal to be one that signifies a change and a stable output signal to be one that signifies no change.

6. Regarding Claims 4 and 5, Levine discloses that the timer varies the interval by altering the duration of the interval with a preset timed amount and that the timer also varies the interval by decreasing a duration of the interval by a predetermined percentage of the interval (see col. 8, lines 31-34 and 50-53). The examiner considers a predefined increment represents either a preset amount or a preset percentage.

7. Regarding Claims 6 and 7, Levine does not explicitly disclose that the timer is limited to a maximum duration for the interval of one month and a minimum duration for the interval of one hour. However, Levine does disclose that the threshold searches can

Art Unit: 3766

be daily or weekly (see col. 12, lines 39-44). The examiner considers that an interval of a day or a week falls within the range of an hour and a month.

8. Regarding Claim 11 Levine discloses that the timer maintains the interval at a duration shorter than or equal to a predetermined interval, for a predetermined time period after a change of the stimulation threshold value (see col. 4, line 65-col. 5, line 4). The examiner considers that the predetermined time period is the length of time before the next threshold test.

9. Regarding Claim 12, Levine discloses that the timer employs an interval of eight hours as the predetermined interval (see col. 4, lines 65-67).

10. Regarding Claim 13, Levine does not disclose that the timer employs a duration of at least one week as the predetermined time period. However, the examiner takes believes that it is common and well-known to allow a stimulating device to pace for a specific time period before concluding, from the threshold searches, that a new interval length is needed. As to making this specific time period more than or equal to one week, it is a matter of obvious design choice. The applicant gives no criticality to the predetermined time period. Any time period would be plausible as long as the following two requirements were fulfilled: 1. The time period is long enough that any change in threshold value created by noise or disturbance is surpassed. 2. The time period is short enough that any change in threshold value created by a real problem in heart activity or device performance does not go ignored. Thus, it would have been obvious to one of ordinary skill in the art to choose a reasonable time period at which to pace the heart with a specific interval before taking into account a change in threshold value

Art Unit: 3766

because not all changes warrant a change in the interval. Furthermore, battery power would be wasted if the stimulator attempted to keep up with every slight change following a newly established interval.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine (US Patent 6,129,746) as applied to claims 1-6 and 11-13 above, and further in view of Levine et al. (US Patent 6,546,288).

13. Regarding Claim 8, Levine ('746) is silent as to the role of loss of capture in determining threshold searches. However, Levine ('288) discloses that the stimulation threshold measuring circuit also makes loss of capture-initiated threshold searches (see col. 5, lines 7-25). The examiner considers that loss of capture and capture go hand in hand when it comes to threshold searches so a clinician would necessarily be observing both parameters just by observing the overall cardiac waveform. Levine ('288) does not disclose that the timer uses the loss of capture-initiated threshold searches and the capture-initiated threshold searches to vary the interval. Yet if one was to use an automated timer to do what the clinician does, then it would be obvious to one of

Art Unit: 3766

ordinary skill in the art at the time of the invention to incorporate loss of capture searches as well as capture searches in varying the interval.

14. Regarding Claims 9 and 10, Levine ('746) discloses that the timer increases the interval if the respective stimulation threshold values, before and after each loss of capture-initiated threshold search, are equal; and that the timer decreases the interval if the respective stimulation threshold values, before and after each loss of capture-initiated threshold search, are not equal (see Claim 1, part 2). The examiner considers that capture and loss of capture can both be derived from the same waveform, and are, therefore, both able to provide their respective threshold value information necessary in determining the interval. The examiner also considers a volatile output signal to be one that signifies a change and a stable output signal to be one that signifies no change.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3766

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NNP  
3/13/06



Robert E. Pezzuto  
Supervisory Patent Examiner  
Art Unit 3766